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Docket No.: CIBT-P01-058  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Lu et al.

Application No.: 09/499526

Confirmation No.: 1398

Filed: February 10, 2000

Art Unit: 1647

For: METHODS AND REAGENTS FOR  
TREATING GLUCOSE METABOLIC  
DISORDERS

Examiner: R. M. Deberry

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
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Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information

as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

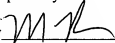
It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 18-1945 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. CIBT-P01-058. A duplicate copy of this paper is enclosed.

Dated: Dec. 30, 2004

Respectfully submitted,

By



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Substitute for form 1449A/B/PTO			<b>Complete If Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	09/499526	
			Filing Date	February 10, 2000	
			First Named Inventor	Kuanghui Lu	
			Art Unit	1647	
			Examiner Name	R. M. Deberry	
Sheet	1	of	4	Attorney Docket Number	CIBT-P01-058

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
RMD	AA	2002/0094346-A1	07-18-2002	Lin	
	AB	4,839,343	06-13-1989	Waeber et al.	
	AC	4,891,357	01-02-1990	Kaira	
	AD	5,604,203	02-18-1997	Balasubramaniam	
	AE	5,696,093	12-09-1997	Tseng et al.	
	AF	5,912,227	06-15-1999	Croom et al.	
	AG	5,939,462	08-17-1999	Connell et al.	
	AH	5,968,819	10-19-1999	Gerald et al.	
RMD	AI	6,013,622	01-11-2000	Bruno et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
RMD	BA	EP-0 992 239-B1	03-12-2003	Banyu Pharmaceuticals	
	BB	WO-00/47219-A2	08-17-2000	Ortho-McNeil Inc.	
	BC	WO-00/68197-A1	11-16-2000	Ortho-McNeil Pharmaceuticals, Inc.	
	BD	WO-01/62737-A2	08-30-2001	Ortho-McNeil Pharmaceuticals, Inc.	
	BE	WO-01/76631-A2	10-18-2001	Cedars-Sinai Medical Center	
	BF	WO-2003/026591-A2	04-03-2003	Imperial College Innovations Ltd. and Oregon Health and Science University.	
RMD	BG	WO-99/15516-A1	04-01-1999	Banyu Pharmaceuticals	

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
RMD	CA	Adrian, T.E., et al., "Human Distribution and Release of a Putative New Gut Hormone, Peptide YY," <i>Gastroenterology</i> , 89:1070-7 (1985).			
	CB	Allen, J.M., et al., "Effects of Peptide YY and Neuropeptide Y on Gastric Emptying in Man," <i>Digestion</i> , 30:255-262 (1984).			
	CC	Asakawa, A., et al., "Mouse pancreatic polypeptide modulates food intake, while not influencing anxiety in mice," <i>Peptides</i> , 20:1445-1448 (1999).			
	CD	Balasubramaniam, A., et al., "Structure-Activity Studies Including a $\psi$ (CH <sub>2</sub> -NH) Scan of Peptide YY (PYY) Active Site, PYY(22-36), for Interaction with Rat Intestinal PYY Receptors: Development of Analogues with Potent in Vivo Activity in the Intestine," <i>J. Med. Chem.</i> , 43:3420-3427 (2000).			
	CE	Batterham, R.L., et al., "Gut hormone PYY3-36 physiologically inhibits food intake," <i>Nature</i> , 418:650-654 (2002).			
RMD	CF	Batterham, R.L., et al., "Inhibition of Food Intake in Obese Subjects by Peptide YY3-36," <i>N Engl J Med</i> , 349(10):941-948 (2003).			

Examiner Signature 9819555_1	Date Considered RMD/ (06/20/2006)
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ALL REFERENCES CONSIDERED EXCEPT AS NOTED THROUGHOUT



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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/499526
		Filing Date	February 10, 2000
		First Named Inventor	Kuanghui Lu
		Art Unit	1647
		Examiner Name	R. M. Deberry
		Attorney Docket Number	CIBT-P01-058
Sheet	2	of	4

RMD	CG	Bonaz, B., et al., "Peripheral peptide YY induces c-fos-like immunoreactivity in the rat brain," Neuroscience Letters, 163:77-80 (1993).	
	CH	Brown, K.K., et al., "A Novel N-Aryl Tyrosine Activator of Peroxisome Proliferator-Activated Receptor- $\gamma$ Reverses the Diabetic Phenotype of the Zucker Diabetic Fatty Rat," Diabetes, 48:1415-1424 (1999).	
	CI	Campfield, L.A., et al., "Recombinant Mouse OB Protein: Evidence for a Peripheral Signal Linking Adiposity and Central Neural Networks," Science, 269(5223):546-549 (1995).	
	CJ	Chen, C.H. and Rogers, R.C., "Central inhibitory action of peptide YY on gastric motility in rats," Am. J. Physiol., 269:R787-R792 (1995).	
	CK	Chen, C.H., et al., "Intracisternal injection of peptide YY inhibits gastric emptying in rats," Regulatory Peptides, 61:95-98 (1996).	
	CL	Clark, J.T., et al., "Neuropeptide Y (NPY)-induced feeding behavior in female rats: comparison with human NPY ([Met <sup>17</sup> ]NPY), NPY analog ([norLeu <sup>4</sup> ]NPY) and peptide YY," Regulatory Peptides, 17:31-39 (1987).	
	CM	Clark, J.T., et al., "Neuropeptide Y and Human Pancreatic Polypeptide Stimulate Feeding Behavior in Rats," Endocrinology, 115(1):427-429 (1984).	
	CN	Corp, E. S., et al., "Effect of fourth ventricular neuropeptide Y and peptide YY on ingestive and other behaviors," The American Physiological Society, 317:323 (1990).	
	CO	Deng, X., et al., "PYY Potently Inhibits Pancreatic Exocrine Secretion Mediated Through CCK-Secretin-Stimulated Pathways but Not 2-DG-Stimulated Pathways in Awake Rats," Digestive Diseases and Sciences, 46(1):156-165 (2001).	
	CP	Eberlein, G. A., et al., "A New Molecular Form of PYY: Structural Characterization of Human PYY (3-36) and PYY (1-36)," Peptides, 10: 797-803 (1999).	
	CQ	Garlicki, J., et al., "Cholecystokinin receptors and vagal nerves in control of food intake in rats," Am. J. Physiol., 258:E40-E45 (1990).	
	CR	Gedulin, B.R., et al., "Assessment of Gastric Emptying from Appearance in Plasma of 3H from Gavage [3-3H] Glucose in Conscious Rats: Effects of Amylin," Gastroenterological, Abstract, Vol. 108, No. 4 (April 1995).	
	CS	Gomez, G., et al., "Intestinal peptide YY: ontogeny of gene expression in rat bowel and trophic actions on rat and mouse bowel," Am. J. Physiol., 268:G71-G81 (1995).	
	CT	Greeley, G.H., et al., "Inhibition of Gastric Acid Secretion by Peptide YY is Independent of Gastric Somatostatin Release in the Rat (42814)," Proceedings of the Society for Experimental Biology and Medicine, 189:325-328 (1988).	
	CU	Grouzmann, E., et al., "Expression and Regulation of Neuropeptide Y in a Rat Insulinoma Cell Line," Endocrinology, Abstract 519B (1993).	
	CV	Guan, et al., "Peptide-YY, a New Partner in the Negative Feedback Control of Pancreatic Secretion," Endocrinology, 128(2):911-916 (1991).	
	CW	Gue, M., et al., "Reversal by NPY, PYY and 3-36 molecular forms of NPY and PYY of intracisternal CRF-induced inhibition of gastric acid secretion in rats," British Journal of Pharmacology, 118:237-242 (1996).	
	CX	Hagan, M.M. and Moss, D.E., "Effect of Naloxone and Antidepressants on Hyperphagia Produced by Peptide YY," Pharmacology Biochemistry and Behavior, 45:941-944 (1993).	
	CY	Halaas, J.L., et al., "Weight-Reducing Effects of the Plasma Protein Encoded by the Obese Gene," Science, 269(5223):543-546 (1995).	
	CZ	Haynes, J.M., et al., "Neuropeptide Y (NPY) and peptide YY (PYY) effects in the epididymis of the guinea-pig: evidence of a pre-junctional PYY-selective receptor," British Journal of Pharmacology, 122:1530-1536 (1997).	
	CA1	Hoenftjen, F., et al., "Role of Circulating Peptide YY in the Inhibition of Gastric Acid Secretion by Dietary Fat in Humans," Scand J Gastroenterol, 35:166-171 (2000).	
RMD	CB1	Iyengar, S., et al., "Characterization of Neuropeptide Y-Induced Feeding in Mice: Do Y1-Y6 Receptor Subtypes Mediate Feeding?," JPET, 289(2):1031-1040 (1999).	

Examiner Signature	ALL REFERENCES CONSIDERED EXCEPT WHERE	Date Considered	THROUGH	/RMD/ (02/20/2008)
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	09/499526
				Filing Date	February 10, 2000
				First Named Inventor	Kuanghui Lu
				Art Unit	1647
				Examiner Name	R. M. Deberry
Sheet	3	of	4	Attorney Docket Number	CIBT-P01-058

RMD	CC1	Kanatani, A., et al., "Role of the Y1 Receptor in the Regulation of Neuropeptide Y-Mediated Feeding: Comparison of Wild-Type, Y1 Receptor-Deficient, and Y5 Receptor-Deficient Mice," <i>Endocrinology</i> , 141(3):1011-1016 (2000).
	CD1	Kato, K., et al., "CGRP Antagonists Enhance Gastric Acid Secretion in 2-h Pylorus-Ligated Rats," <i>Peptides</i> , 16(7):1257-1262 (1995).
	CE1	Kawakubo, K., et al., "Intracisternal PYY inhibits gastric lesions induced by ethanol in rats: role of PYY-preferring receptors?," <i>Brain Research</i> , 854:30-34 (2000).
	CF1	Kimmel, J.R., et al., "Isolation and Characterization of Chicken Insulin," <i>Endocrinology</i> , 83:1323-1330 (1968).
	CG1	Kopelman, P.G., "Obesity as a medical problem," <i>Nature</i> , 404:635-643 (2000).
	CH1	Kushji, A., et al., "Obesity and mild hyperinsulinemia found in neuropeptide Y-Y1 receptor-deficient mice," <i>Proc. Natl. Acad. Sci. USA</i> , 95:15659-15664 (1998).
	CI1	Lloyd, K.C.K., et al., "Inhibitory effect of PYY on vagally stimulated acid secretion is mediated predominantly by Y1 receptors," <i>Am. J. Physiol.</i> , 270:G123-G127 (1996).
	CJ1	Malaisse-Lagae, F., et al., "Pancreatic polypeptide: A possible role in the regulation of food intake in the mouse," <i>Experientia</i> 33, 915-917 (1977).
	CK1	Marsh, D.J., et al., "Role of the Y5 neuropeptide Y receptor in feeding and obesity," <i>Nature Medicine</i> , 4(6):718-721 (1998).
	CL1	Michel, M.C., et al., "XVI. International Union of Pharmacology Recommendations for the Nomenclature of Neuropeptide Y, Peptide YY, and Pancreatic Polypeptide Receptors," <i>Pharmacological Reviews</i> , 50(1):143-150 (1998).
	CM1	Morley, J.E., et al., "Modulation of food intake by peripherally administered amylin," <i>Am. J. Physiol.</i> , 267:R178-R184 (1994).
	CN1	Morley, J.E., et al., "Peptide YY (PYY), a potent orexigenic agent," <i>Brain Research</i> , 341:200-203 (1985).
	CO1	Munson, P.J. and Rodbard, D., "LIGAND: A Versatile Computerized Approach for Characterization of Ligan-Binding Systems," <i>Analytical Biochemistry</i> , 107:220-239 (1980).
	CP1	Nakajima, M., et al., "Effects of Pancreatic Polypeptide Family Peptides on Feeding and Learning Behavior in Mice," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 268(2):1010-1014 (1994).
	CQ1	Naslund, E., et al., "Energy intake and appetite are suppressed by glucagon-like peptide-1 (GLP-1) in obese men," <i>International Journal of Obesity</i> , 23:304-311 (1999).
	CR1	Okada, S., et al., "Peripherally Not Centrally Administered Peptide YY (PYY) Decreases High Fat Diet Intake," <i>Endocrinology</i> , Abstract 520B (1993).
	CS1	Pappas, T.N., et al., "Peptide YY Release by Fatty Acids is Sufficient to Inhibit Gastric Emptying in Dogs," <i>Gastroenterology</i> , 91:1386-9 (1986).
	CT1	Pelleymounter, M.A., et al., "Effects of the Obese Gene Product on Body Weight Regulation in Ob-Ob Mice," <i>Science</i> , 269(5223):540-543 (1995).
	CU1	Rissanen, A., et al., "Risk of disability and mortality due to overweight in a Finnish population," <i>Br Med J</i> , 301:835-837 (1990).
	CV1	Savage, A.P., et al., "Effects of peptide YY (PYY) on mouth to caecum intestinal transit time and on the rate of gastric emptying in healthy volunteers," <i>Gut</i> , 28:166-170 (1987).
CW1	Scatchard, G., "The Attractions of Proteins For Small Molecules and Ions," <i>Annals New York Academy of Sciences</i> , pp. 660-672.	
CX1	Schwartz, M.W., et al., "Central nervous system control of food intake," <i>Nature</i> , 404:661-671 (2000).	
CY1	Stanley, B.G., et al., "Paraventricular Nucleus Injections of Peptide YY and Neuropeptide Y Preferentially Enhance Carbohydrate Ingestion," <i>Peptides</i> , 6:1205-1211 (1985).	
CZ1	Surwit, R.S., et al., "Differential Effects of Fat and Sucrose on the Development of Obesity and Diabetes in C57BL/6J and A/J Mice," <i>Metabolism</i> , 44(5):645-651 (1995).	
RMD	CA2	Taniguchi, H., et al., "Pharmacological profile of T-0632, a novel potent and selective CCK(a).

Examiner Signature	ALL REFERENCES CONSIDERED EXCEPT WHERE SHOWN OTHERWISE THROUGH RMD (02/20/2006)	Date Considered
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/499526
		Filing Date	February 10, 2000
		First Named Inventor	Kuanghui Lu
		Art Unit	1647
		Examiner Name	R. M. Deberry
Sheet	4	of	4
		Attorney Docket Number	CIBT-P01-058

RMD		receptor antagonist, in vivo," European Journal of Pharmacology, 312:227-233 (1996).	
	CB2	Tatemoto, K., "Neuropeptide Y: Complete Amino Acid Sequence of the Brain Peptide," Proc. Natl. Acad. Sci. USA, 79:5485-5489 (1982).	
	CC2	Tatemoto, K., et al., "Neuropeptide Y-a novel brain peptide with structural similarities to peptide YY and pancreatic polypeptide," Nature, 296:659-660 (1982).	
	CD2	Ueno, N., et al., "Decreased Food Intake and Body Weight in Pancreatic Polypeptide-Overexpressing Mice," Gastroenterology, 117:1427-1432 (1999).	
	CE2	Verchere, C. B., et al., "Major Species Variation in the Expression of Galanin mRNA in Mammalian Celiac Ganglion", Endocrinology, Abstract 517B (1993)	
	CF2	Wang, Z. L., et al., "Co-Release of Neuropeptide Y With Insulin Following Dexamethasone", Endocrinology, Abstract 518B (1993)	
	CG2	Widdowson, P. S., et al., "Distribution of [Leu31,Pro34]NPY-sensitive, BIBP3226-insensitive (125I)PYY(3-36) binding sites in rat brain: possible relationship to Y5 NPY receptors," Brain Research, 778:242-250 (1997).	
	CH2	Wiley, J.W., et al., "Mechanism of Action of Peptide YY to Inhibit Gastric Motility," Gastroenterology, 100:865-872 (1991).	
	CI2	Yang, H. and Tache, Y., "PYY in brain stem nuclei induces vagal stimulation of gastric acid secretion in rats," Am. J. Physiol., 268:G943-G948 (1995).	
	CJ2	Yang, H., et al., "PYY-preferring receptor in the dorsal vagal complex and its involvement in PYY stimulation of gastric acid secretion in rats," British Journal of Pharmacology, 123:1549-1554 (1998).	
	CK2	Yoshinaga, K., et al., "Structural requirements of peptide YY for biological activity at enteric sites," Am. J. Physiol., 263:G695-G701 (1992).	
	CL2	Young, AA, et al., "Genetically Obese (OB/OB) Mice Are More Sensitive To Amylin and Endotoxin Induced Suppression of Food Intake", Amylin Pharmaceuticals Inc., Program & Abstracts, Vol. 1: June 12 & 13 (1996).	
RMD	CM2	Zai, H., et al., "Effect of peptide YY on gastric motor and secretory activity in vagally innervated and denervated corpus pouch dogs," Regulatory Peptides, 61:181-188 (1996).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Application No. (if known): 09/499526


Attorney Docket No.: CIBT-P01-058

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Supplemental Information Disclosure Statement (4 pages)

IDS by Applicant – Form SB/08 (81 References)

References (AA-AI; BA-BG; CA-CL2)

Fee Transmittal (1 page)

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<p>Effective on 12/08/2004.          Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4518).</p> <p><b>FEE TRANSMITTAL</b>  <b>For FY 2005</b></p> <p><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27</p>		<p><b>Complete if Known</b></p> <p>Application Number 09/499552          Filing Date February 10, 2000          First Named Inventor Kuanghui Lu          Examiner Name R. M. Deberry          Art Unit 1647          Attorney Docket No. CIBT-P01-058</p>	
<p><b>TOTAL AMOUNT OF PAYMENT</b> (\$)</p>		<p>180.00</p>	

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### FFC CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
	Small Entity	Small Entity	Small Entity	Small Entity	Small Entity	Small Entity	
<u>Application Type</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>	<u>Fee (\$)</u>	<u>Fees Paid (\$)</u>
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

## 2. EXCESS CLAIM FEES

### Fee Description

Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

### Multiple dependent claims

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>
<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>			
<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	

### 3. APPLICATION SIZE FEE


If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- 100 =	/50	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

**Non-English Specification.** \$130 fee (no small entity discount)

Other (e.g., late filing surcharge):	1806 Submission of an Information Disclosure Statement	180.00
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SUBMITTED BY			
Signature		Registration No. (Attorney/Agent)	54,408 Telephone (617) 951-7653
Name (Print/Type)	Melissa S. Rones, Ph.D.		Date Dec. 30, 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 12/30/04 Signature: [Signature] (Ginny Blundell)